This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-F-0001
CUSTOMER NUMBER: 1210

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Usda-Ars-Poisionous Plant Research Lab
1150 East 1400 North
Logan, UT 84321

Telephone: (801) -752-2941

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters	37	13			13
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbils	7	1			1

All other animals used at this facility are used for agricultural research and are not covered under the animal welfare act (AWA).

mailed to Lewis 11/19/04

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*

DATE SIGNED 11/19/04

ch is obsolete.)

DEC - 9 2004

United Stated Department of Agriculture
Agricultural Research Service

ANNUAL REPORT OF RESEARCH FACILITY
(Required For Each Reporting Facility Where Farm Animals Are Held)

ARS TEMPORARY FORM 85 - 86

1. DATE OF REPORT: 11/18/04

2. HEADQUARTERS RESEARCH FACILITY (Name & Address)
USDA-ARS-NPA
Natural Resources Research Center
2150 Centre Ave Bldg D STE 300
Fort Collins CO 80526-8119

3. REPORTING FACILITY (Name & Address)
USDA-ARS-Poisonous Plant Res. Lab
1150 E 1400 N
Logan Ut 84341

INSTRUCTIONS

Reporting Facility - complete items 1 through 30 and submit to your Headquarters Facility. Attach additional sheets if necessary.

Headquarters Facility - complete items 31 through 33 and submit on or before December 1 of each year for the preceding Federal fiscal year (October 1 to September 30) to Dr. Robert Heckert, USDA-ARS-NPS, GWCC 4-2176 -Beltsville, Maryland 20705-5138.

REPORT OF FARM ANIMNALS USED IN ACTUAL RESEARCH, TESTING, OR EXPERIMENTATION INCLUDING PRODUCTION RESEARCH

A. Farm Animals	B. New Animals Added this Year	C. Number of animals used in research, experiments, or tests involving no pain or distress.	D. Research, experiments, or tests where appropriate anesthetic, analgesic, or tranquilizer drugs were administered to avoid pain or distress.	E. Research, experiments, or tests involving pain or distress without administration of appropriate anesthetic, analgesic, or tranquilizer drugs. (Attach brief explanation.)	F. TOTAL NO. of Animals (Cols. C + D + E)
4. Cattle	32	32			32
5. Swine					Ø
6. Sheep	164	219			219
7. Goats	34	72			72
8. Horses	3		3		3
9. Chickens					Ø
10. Turkeys					Ø
11. Quail					Ø
12. Pheasants					Ø
13. ~~Other Avian Species (Specify)~~ MICE	100	100			100
14. HAMSTER	50	13			63
15. GERBIL		1			1

CERTIFICATION BY ATTENDING VETERINARIAN FOR REPORTING FACILITY OR INSTITUTION COMMITTEE

I (We) hereby certify that the type and amount of analgesic, anesthetic, and tranquilizing drugs used on animals during actual research, testing or experimentation including post-operative and post-procedural care was deemed appropriate to relieve pain and distress for the subject animal.

(b)(6), (b)(7)c

17. TITLE: Veterinarian/Professor	18. DATE SIGNED: 11/1/04
20. TITLE: scientist	21. DATE SIGNED: 10/29/04
23. TITLE: Statistical consultant	24. DATE SIGNED: 11/2/04
26. TITLE: scientist	27. DATE SIGNED: 11/4/04
29. TITLE: Scientist	30. DATE SIGNED: 11/9/04

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

I certify that the above is true, correct, and complete and that professionally acceptable standards governing care, treatment, and use of farm animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs during actual research, testing, or experimentation including post-operative and post-procedural care are being followed by the above research facilities or sites.

32. TITLE:	33. DATE SIGNED: 10/20/04

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150

See reverse side for additional information

Interagency Report Control No. 0180-DOA-AN

DEC - 9 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-F-0001
CUSTOMER NUMBER: 1210

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Usda-Ars-Poisionous Plant Research Lab
1150 East 1400 North
Logan, UT 84321

Telephone: (801) -752-2941

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters	37	13			13
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbils	7	1			1

All other animals used at this facility are used for agricultural research and are not covered under the animal welfare act (AWA).

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIG

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*

DATE SIGNED 11/19/04

APH ch is obsolete.)

DEC - 9 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

COPY FOR YOUR INFORMATION

1. CERTIFICATE NUMBER: 87-R-0001

CUSTOMER NUMBER: 12

FORM APPROVED
OMB NO. 0579-0036

University Of Utah
50 North Medical Drive, 1c311
Salt Lake City, UT 84132

Telephone: (801) -581-6840

resubmit 12/01/04 no changes "A" by Dr. Watland 05/17/05

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	17	258	0	275
5. Cats	0	2	72	0	74
6. Guinea Pigs	0	80	207	522	809
7. Hamsters	0	11	10	0	21
8. Rabbits	0	232	703	0	935
9. Non-human Primates	0	0	4	0	4
10. Sheep	0	55	3	0	58
11. Pigs	0	6	58	0	64
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		4/25/05

APHIS FORM 7023 (Previous edition is obsolete.)

APR 27 2005

Registration Number: 87-R-0001/12
Number of animals used in this study: 522
Species: Guinea pigs

Description of procedure
The procedure performed is a skin sensitization test. The animals utilized in the test experience slight pain that is occasionally more than momentary. It consists of slight skin irritation.

Scientific justification
Pain relievers in general, are anti-inflammatory and may interfere with optimization of the potential for detection of contact sensitization in this study design. Since inflammation is a component of the sensitization response being evaluated, introduction of agents that influence an inflammation response would most likely interfere with the evaluation of the potential of the test article to elicit a sensitization response.

Federal regulations requiring this procedure
International Standards Organization (ISO) 10993-1, parts 10 and 11

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

THE UNIVERSITY OF UTAH

Vice President for Research
201 S Presidents Circle Rm 210 Salt Lake City, Utah 84112-9011 (801) 581-7236 FAX (801) 585-6212

April 8, 2005

Richard Watkins, D.V.M.
Supervisory Animal Care Specialist
Western Region, Animal Care
2150 Centre Avenue, MS 3W11
Fort Collins, CO 80526

Reference: Registration # 87-R-0001, Customer # 12

Dear Dr. Watkins,

I am writing in response to your letter dated March 25, 2005 in which you requested additional information regarding our facility's annual report.

First, please find enclosed an amended annual report which was submitted electronically on March 2, 2005. This report corrects the previous submission received by APHIS on October 25, 2004.

Second, in regard to further clarification for the justification to withhold topical anesthetic or analgesic, I am enclosing a copy of a letter sent to [redacted] The letter responds to concerns raised by [redacted] in connection with the guinea pigs listed in category E and addresses specifically the reason that an anesthetic/analgesia would adversely affect the study results.

Finally, I am enclosing a copy of ISO 10993, part 10, section 6, which describes the maximization test method. While this document does not specifically indicate that pain and/or distress relieving drugs may not be used, it does specify the maximization method for use when investigating erythema and/or oedema reactions (see table 6). Please note our citation of ISO 10993 on Form 7023 is in response to item 6 of the Column E Explanation section which asks "What, if any federal regulations require this procedure?". Please refer to the letter mentioned above for a specific justification for not using pain relieving drugs.

Thank you for your consideration in this matter. Please contact us if you have any further questions.

Enclosures

PDEF
Preclinical Drug Evaluation Facility

University of Utah
421 Wakara Way, Suite 318
Salt Lake City, Utah 84108
(801) 581-7178 Voice
(801) 585-3614 Fax

March 1, 2005

(b)(6), (b)(7)(C)

COPY
INFO

Dear (b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

I am writing in response to your letter dated February 17, 2005, based upon concerns raised by (b)(6), (b)(7)(C) regarding the annual USDA report. In regard to item #1, our current use of the Guinea Pig Maximization Test is limited to FDA submission/regulation, in particular evaluation of medical devices and compounds for biocompatibility assessment. The Murine Local Lymph Node Assay (LLNA) has been accepted as an alternative to the Guinea Pig Maximization Test by the EPA for use in evaluating certain chemicals based upon the ICCVAM/NIH publication 99-4494, February 1999. This publication presented the strength of the LLNA; however, the usefulness of the method for testing mixtures and extracts was not addressed in the proposal. Additionally, the EPA and EMEA guidance document state that the LLNA may not be appropriate for all types of test materials, such as certain metallic compounds, high molecular weight proteins, strong dermal irritants and materials that do not sufficiently adhere to the ear for an acceptable period of time during treatment. When using the LLNA, particular care should be taken to ensure that hydrophilic materials are incorporated into a vehicle system that wets the skin and does not immediately run off. Thus, wholly aqueous vehicles or test materials and runny liquids are to be avoided (EPA Health Effects Test Guideline – OPPTS 870.2600, Skin Sensitization). The materials that we evaluate under FDA and ISO Standards are aqueous and oil extracts of medical devices and thus would not be candidates for use in the LLNA. Therefore, the Guinea Pig Maximization Test is considered to be the most appropriate animal model to evaluate sensitization potential for devices and other compounds which employ aqueous extracts, as well as those that are liquid in nature.

In regard to item #2, I had performed a literature search using MEDLINE (September 26, 2003) with the key words "drugs", "medical devices", "pharmaceuticals", "guinea pigs", "drug effects", "pain", "distress", "animal testing alternatives", "anesthesia", "analgesia", "non-animal model", and "cell cultures" prior to protocol submission. I have since performed an additional literature search using MEDLINE (February 28, 2005) with the key words "analgesia", "anti-inflammatory response" and "guinea pigs". The years covered by these searches were 1965-present. Based upon these searches, I was unable to find an analgesia method which does not effect the inflammatory reaction. In addition, I have spoken to several veterinarians and veterinary pathologists, as well as a researcher from the Anesthesiology Department in the School of Medicine of the University of Utah. None of these individuals are aware of any alternatives which would not, in some way, affect the inflammatory response that we induce in this study design.

I hope that the information provided in this letter is sufficient. If there are any other issues that need to be addressed or if you require additional information regarding the issues addressed herein, please let me know.

Sincerely,

(b)(6), (b)(7)(C)

www address:
http://biotech.genetics.utah.edu/pdef/

APR 1 1 2005

DRAFT INTERNATIONAL STANDARD ISO/DIS 10993-10.2

ISO/TC 194 Secretariat: DIN

Voting begins on 1993-11-11 Voting terminates on 1994-01-11

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Biological evaluation of medical devices —

Part 10:
Tests for irritation and sensitization

Évaluation biologique des dispositifs médicaux —
Partie 10: Essais d'irritation et de sensibilisation

UDC [615.46/.47].076:616-002

Descriptors: medical equipment, surgical equipment, surgical implants, dental equipment, dental materials, tests, biological tests, skin irritation.

In accordance with the provisions of Council Resolution 15/1993, this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

6.2 Maximization sensitization test

6.2.1. Principle

Assessment of the potential of the material under test to produce skin sensitization in the guinea pig.

6.2.2. Test material

If the test material is a solid or a liquid it shall be prepared according to the procedures described in annex A.

If the test material is an extract, it shall be prepared as described in annex B.

6.2.3. Animals and husbandry

Healthy young adult albino guinea-pigs of either sex from a single outbred strain, weighing 300 to 500g at the start of the test shall be used. If female animals are used they shall be nulliparous and non-pregnant.

The animals shall be acclimatized and cared for according to procedures described in annex C.

For testing powders or liquids, a minimum of ten animals shall be treated with the test material and a minimum of five animals will act as a control group. Additional animals shall be used for the preliminary test.

For testing extracts, a minimum of ten animals shall be treated with each extract and a minimum of five animals will act as a control for each solvent. Additional animals shall be used for the preliminary test.

NOTE It may be necessary to double the number of animals in order to confirm weak sensitizers. See OECD Guideline No.406.

6.2.4. Test procedure

6.2.4.1. Preparation

Clip the fur on all treatment sites, the day prior to treatment.

For intradermal injections inject 0.1ml per site.

For all topical applications, saturate a patch of filter paper of the appropriate dimensions with the test material and apply the patch to the clipped skin surface under a retaining dressing.

NOTE e.g. an occlusive dressing wound around the torso of the animal.

6.2.4.2. Preliminary tests

NOTE The preliminary tests are intended to determine the concentrations of the test materials to be used in the main test described in 6.2.4.3.

Pretreat all animals with Freunds Complete Adjuvant.

Inject a range of concentrations of the test material (in the selected solvent) intradermally into at least two animals.

Select for the intradermal induction phase in the main test, the highest concentration that does not cause extensive destruction of the skin and does not otherwise adversely affect the animals.

Topically apply a range of concentrations of the test material to the flanks of at least three additional animals. Remove the occlusive dressings and patches after 24 h and assess the application sites for erythema and oedema using the grading given in table 7.

Select:

a) if possible, for the topical induction phase in the main test, the highest concentration that causes slight erythema but does not otherwise adversely affect the animals;

b) for the topical challenge phase in the main test, the highest concentration that causes no erythema.

6.2.4.3. Main test

6.2.4.3.1. Intradermal induction phase

Make a pair of 0.1 ml intradermal injections of each of the following, into each animal, at the injection sites (1, 2 and 3) as shown in figure 3 in the clipped intrascapular region.

(1) A 50 : 50 mixture of Freund's Complete Adjuvant mixed with the chosen solvent. Water for injection or physiological saline (BP,USP or equivalent) for water soluble substances. For non-aqueous soluble substances, examples of solvents are given in Annex B 2.10.

(2) The test material at the concentration selected in the preliminary tests, inject the control animals with the solvent alone.

(3) The test material at the concentration used in (2), emulsified in a 50 : 50 mixture of Freund's Complete Adjuvant and the solvent; inject the control animals with the solvent emulsified in adjuvant.

6.2.4.3.2. Topical induction phase

Seven days after completion of intradermal induction phase, administer the test material by topical application to the intrascapular region of each animal, using 20 mm x 40 mm filter paper, so as to cover the intradermal injection sites. Use the concentration selected in 6.2.4.2.a). Secure with an occlusive dressing. Remove the dressings and patches after 48 +/- 2 h.

Treat the control animals similarly, using the solvent alone.

If the maximum concentration that can be achieved in 6.2.4.2.a) does not produce irritation, pre-treat the area with 10% sodium lauryl sulphate in petrolatum massaged into the skin 24 +/- 2h before the topical induction patch is applied. Treat the control groups similarly.

6.2.4.3.3. Challenge phase

At least 14 days after completion of the topical induction phase, challenge all test and control animals with the test material. Administer the test material by topical application to one flank of each animal using appropriate patches soaked in the test material at the concentration selected in 6.2.4.2.b). Secure with an occlusive dressing. Remove the dressings and patches after 24 +/- 2h.

NOTE Dilutions of this concentration may also be applied to other untreated sites in a similar manner.

6.2.5. Observation of animals

Observe the appearance of the challenge skin sites of the test and control animals 24 h, 48 h and 72 h after removal of the dressings. Describe and grade the skin reactions for erythema and eschar according to the grading given in table 6 for each challenge site and at each time interval observed.

6.2.6. Evaluation of results

Grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen on control animals. If grades of 1 or greater are noted on control animals, then the reactions of test animals which exceed the most severe control reaction are presumed to be due to sensitization.

NOTE Occasionally, test animals may have a greater incidence of skin reactions which are comparable in intensity to controls, without a single animal being more reactive. In these instances, a rechallenge may be necessary to clearly define the response. If necessary a rechallenge shall be carried out approximately 7 days after the first challenge. The method used shall be as described for the first challenge, using the other flank of the animal.

6.2.6. Presentation of results

The test report shall include:

a) a description of the test material(s) or device;
b) the intended use/application of the test material(s) or device;
c) a detailed description of the method employed in preparing the test material or device;
d) the test animals;
e) method of application to the test sites;
f) how the site readings were performed and a record of the observations;
g) assessment of the results.

APR 11 2005

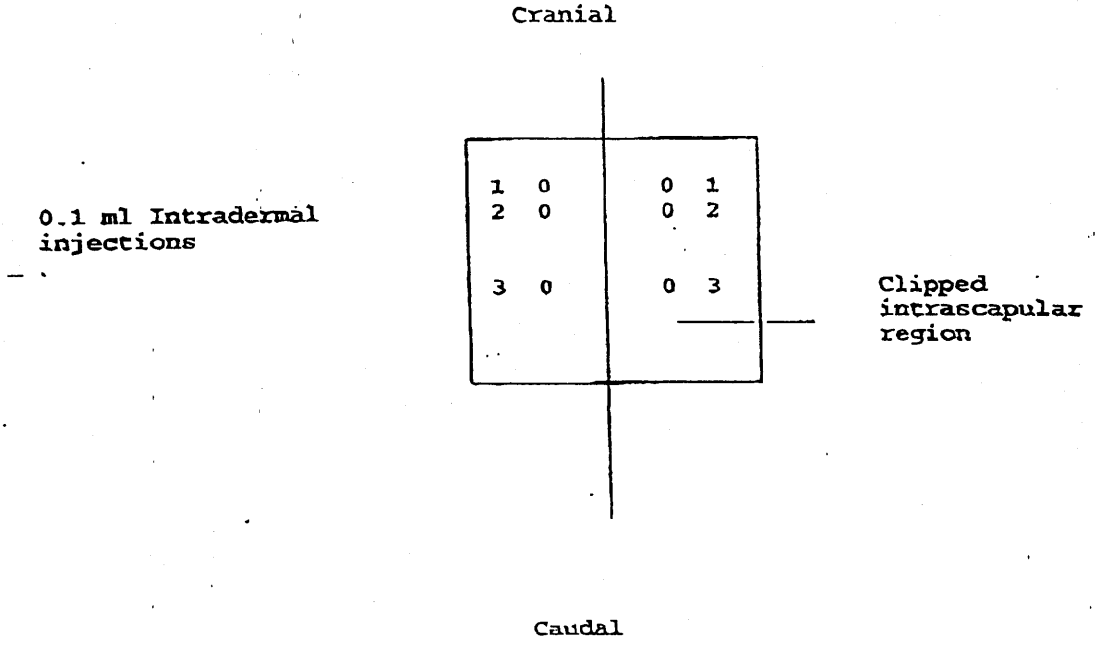
Table 6 - Classification system for skin reactions

Reaction	Numerical Grading
Erythema	
No erythema	0
Slight erythema	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema to slight eschar formation	4
Oedema	
No oedema	0
Slight oedema	1
Well-defined oedema	2
Moderate oedema	3
Severe oedema	4

NOTE 1. Other adverse changes of the skin sites shall be recorded and reported.

NOTE 2. For the purposes of standardization the grading system has been modified from the original method.

Figure 3 - Location of intradermal injection sites



This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.: 11-15-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-R-0002
CUSTOMER NUMBER: 2

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Utah State University
Vp For Research/14500 Old Main Hill
Logan, UT 84322

Telephone: (435) -797-1180

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (**Attach additional sheets if necessary or use APHIS Form 7023A**)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	178	100	0	278
7. Hamsters	0	1094	145	0	1239
8. Rabbits	0	6	0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Chinchillas	2	0	0	0	0
*Cougars	0	0	21	0	21

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/8/04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

*Utilized in Field Research

NOV -9 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
87-R-0002

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Utah State University
VP For Research/14500 Old Main Hill
Logan, UT 84322

Telephone: (435)-797-1180

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F TOTAL NO. OF ANIMALS (Cols. C + D + E)
*Mule Deer	0	63	0	0	63
*Raccoons	0	0	25	0	25
*Pallid Bat	0	28	0	0	28
*Big Brown Bat	0	10	0	0	10
*Spotted Bat	0	1	0	0	1
*Silver-Haired Bat	0	1	0	0	1
*W. Small Footed Myotis	0	67	0	0	67
*W. Longeared Myotis	0	5	0	0	5
*Little Brown Myotis	0	1	0	0	1
*Fringed Myotis	0	63	0	0	63
*Long Legged Myotis	0	1	0	0	1
*Yuma Myotis	0	84	0	0	84
*W. Pipistrelle	0	13	0	0	13
*Coyote	0	47	0	0	47
*Pocket Mouse	0	105	0	0	105
*Deer Mouse	0	730	0	0	730
*Brush Mouse	0	15	0	0	15
*Pinon Mouse	0	2	0	0	2

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/4/04

APHIS FORM 7023A
(AUG 91)

NOV - 9 2004

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO.
87-R-0002

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Utah State University
VP For Research/14500 Old Main Hill
Logan, UT 84322

Telephone: (435)-797-1180

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach adiditional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations — 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F TOTAL NO. OF ANIMALS (Cols. C + D + E)
Desert Wood Rat	0	3	0	0	3
Kangaroo Rat	0	9	0	0	9
Harvest Mouse	0	6	0	0	6
Antelope Squirrel	0	4	0	0	4
Mongoose	0	9	0	0	9
Wild Rat	0	16	0	0	16
Least Chipmunk	0	111	0	0	111
Uinta Chipmunk	0	29	0	0	29
Voles	0	65	0	0	65
Uinta Ground Squirrel	0	3	0	0	3
Flying Squirrel	0	2	0	0	2
Pocket Gopher	0	1	0	0	1
Rock Squirrel	0	1	0	0	1
Short Tail Weasel	0	1	0	0	1
Long Tail Weasel	0	1	0	0	1

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/04/04

APHIS FORM 7023A
(AUG 91)

-9 2004

PART 1 - HEADQUARTERS

ANNUAL REPORT OF RESEARCH FACILITY
Utah State University
Certificate Number: 87-R-0002
November 04, 2004

3.) Reporting Facility

Laboratory Animal Research Center
Field

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 87-R-0003 **CUSTOMER NO.** 3

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BRIGHAM YOUNG UNIVERSITY
A-261, ASB
PROVO, UT 84602-1231

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS*(sites)*

BRIGHAM YOUNG UNIVERSITY
PROVO, UT 84602-1231

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs		7	7		14
5. Cats		5	10		15
6. Guinea Pigs		3			3
7. Hamsters					
8. Rabbits		15	2		17
9. Non-Human Primates					
10. Sheep					
11. Pigs		4			4
12. Other Farm Animals					
Goat		4			4
13. Other Animals					
Ferret		1			1
Chinchilla		1			1
Bear			12		12

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/03/2004

APHIS FORM 7023 **(AUG 91)**

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 87-R-0003 **CUSTOMER NO.** 3

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

BRIGHAM YOUNG UNIVERSITY
A-261, ASB
PROVO, UT 84602-1231

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Llama		4			4
Alpaca		4			4
Horse		2			2

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/03/2004

APHIS FORM 7023A (AUG 91) **(Replaces VS FORM 18-23 (Oct 88), which is obsolete**

PART 1 - HEADQUARTERS

APHIS Form 7023 Additional Reported Sites

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number: 87-R-0003
Customer Number: 3
Facility: BRIGHAM YOUNG UNIVERSITY
A-261, ASB
PROVO, UT 84602-1231

Veterinary Technology Complex
51 E 2230 N
Provo, UT 84602

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.: 12-2-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 87-R-0004
CUSTOMER NUMBER: 4

FORM APPROVED
OMB NO. 0579-0036

LDS Hospital - Office of Research
8th Avenue & C Street
Salt Lake City, UT 84143
ATTN: IACUC Chairman

Tele: 1-801-408-4217

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	39	6	0	0	6
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
140 Non-regulated Rats	0	0	30	0	30

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and apr Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
	11-29-04

; obsolete.)

(AUG 91)

DEC - 1 2004

The Intermountain Health Care (IHC) IACUC program at LDS Hospital supervises animal research at the following laboratory facilities:

Medical Physics
825 North 300 West#420
Salt Lake City, UT 84103
Facility Supervisor: (b)(6), (b)(7)c

Advanced Interventional Technologies Laboratory
803 North 300 West
Salt Lake City, UT 84103
Facility Supervisor: (b)(6), (b)(7)c

Surgical Research Laboratory
LDS Hospital
8th Avenue and C Street
Salt Lake City, UT 84103
Facility Supervisor: (b)(6), (b)(7)c

F. Nephi and Addie C. Griggs Research Lab
LDS Hospital
8th Avenue and C Street
Salt Lake City, UT 84103
Facility Supervisor: (b)(6), (b)(7)c

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.: 0445104

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-R-0008
CUSTOMER NUMBER: 5

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Weber State University
1027 University Circle
Ogden, UT 84408
(801) 626-7619

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

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3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SI	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		9/28/04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

OCT 1 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.: 11-15-04 Larris

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 87-R-0013
CUSTOMER NUMBER: 1013

FORM APPROVED
OMB NO. 0579-0036

N P S Pharmaceuticals
420 Chipeta Way, Suite 240
Salt Lake City, UT 84108

Telephone: (801) -583-4939

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATU

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED 1/9/04

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(AUG 91)

NOV 10 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 87-R-0018 **CUSTOMER NO.** 1629

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

FRONTIER BIOMEDICAL, INC.
1785 NORTH 730 WEST
LOGAN, UT 84321

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS*(sites)*

FRONTIER BIOMEDICAL, INC.
LOGAN, UT 84321

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	1		19		19
9. Non-Human Primates					
10. Sheep	80		62		62
11. Pigs	8		26		26
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		11/22/2004

APHIS FORM 7023 **(AUG 91)**

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 215

See attached form for additional information.

Interagency Report Control No.: 11-2-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 87-R-0020
CUSTOMER NUMBER: 1831

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Utah Artificial Heart Inst.
803 North 300 West
Salt Lake City, UT 84103

Telephone: (801) -323-1100

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			3		3
9. Non-human Primates					
10. Sheep			8		8
11. Pigs			7		7
12. Other Farm Animals					
Calves			16		16
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

Print)

DATE SIGNED 10/5/04

CT 88), which is obsolete.)

(AUG 91)

OCT -8 2004

Attachment for APHIS FORM 7023

Facility Sites:

Utah Artificial Heart Institute
803 North 300 West
Salt Lake City, UT 84103
County: Salt Lake
Telephone: (801) 323-1100

Mountain Medical Surgical Center
5323 So. Woodrow
Murray, UT 84107
County: Salt Lake
Contact Person (b)(6), (b)(7)c
Phone Number:

Certificate number: 87-R-0020
Customer number: 1831

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information. W: J:AQUIS

Interagency Report Control No.: 11-7-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 87-R-0021
CUSTOMER NUMBER: 20654

FORM APPROVED
OMB NO. 0579-0036

Utah Career College
1902 West 7800 South
West Jordan, UT 84088

Telephone: (801) -304-4224

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this repor	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	2	5	21	0	26
5. Cats	0	4	35	0	39
6. Guinea Pigs	0	0	2	0	2
7. Hamsters	0	7	0	0	7
8. Rabbits	0	2	0	0	2
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
				0	
13. Other Animals				0	
ferrets		3	0	0	3
				0	
				0	

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
	10-19-04

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

OCT 22 2004

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

See attached form for additional information.

Interagency Report Control No.: 11-1-04

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 87-R-0022
CUSTOMER NUMBER: 21308

FORM APPROVED
OMB NO. 0579-0036

Ibex Preclinical Research, Inc.
1072 West Rsi Drive
Logan, UT 84321

Telephone: (435) -881-1496

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	
6. Guinea Pigs	0	0	0	0	
7. Hamsters	0	0	0	0	
8. Rabbits	0	0	0	0	
9. Non-human Primates	0	0	0	0	0 Per 11-1-04 EHC
10. Sheep	18	2	0	0	20
11. Pigs	30	0	3	0	3
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and app Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF R.F.C. OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF R.F.C. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED 10/4/04

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